

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/526,802 03/16/00 PARASRAMPURIA

J 4600-0131.30

022798 HM12/1004
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EXAMINER

QAIZI,S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED:

10/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|--------------------------------------|-------------------------------------------|
| Office Action Summary | Application No. 09/526,802 | Applicant(s) Parasampuria et al |
| | Examiner Sabiha Qazi | Art Unit 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on interview on 7/17/01.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-35 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 1-35 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) Interview Summary (PTO-413) Paper No(s). _____

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

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Restriction/Election - 35 U.S.C. 121

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4 are drawn to pharmaceutical formulations of DHEA, classified in class 514 , subclass 169+.
- II. Claims 5-10 are drawn to method for preparing formulations, classified in class 514 , subclass 169+.
- III. Claims 11-15 are drawn to method of administering DHEA, treatment of systemic lupus erythematosus, classified in class 514 , subclass 169+.
- IV. Claims 11-16 are drawn to prevention or reduction of loss of bone density, classified in class 514 , subclass 169+.
- V. Claims 11-17 are drawn to treatment of chronic fatigue syndrome or fibromyalgia, classified in class 514 , subclass 169+.
- VI. Claims 18-21 are drawn to, pharmaceutical formulation of DHEA, classified in class 514 , subclass 169+.
- VII. Claims 22-27 are drawn to method of preparation of formulation, classified in class 514 , subclass 169+.
- VIII. Claims 28-32 are drawn to method of administering DHEA for the treatment of systemic lupus, classified in class 514 , subclass 169+.
- XI. Claims 28-33 are drawn to prevention or reduction of loss of bone density, classified in class 514 , subclass 169+.
- X. Claims 28-34 are drawn to treatment of chronic fatigue syndrome or fibromyalgia, classified in class 514 , subclass 169+.
- XI. Claim 35 is drawn to a method of controlling the bioavailability of a DHEA formulation, classified in class 514, subclass 169+.

If applicants want to elect the invention other than those cited above, they may elect a species and Examiner will build a subgenus falling in the species for examination.

The inventions of groups I-XI are distinct, each from the other because of the following reasons:Claims are drawn to different formulation, method of making and method of use. Each of them require a separate database search. It would be burden on the Examiner to search all the

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instantly claimed invention in this application. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art and of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Attorney LeeAnn Gorthy on 10/18/00 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I). It is suggested that in order to advance prosecution, the non elected subject matter be canceled when responding to this office action.

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

10/2/01



SABIHA QAZI, PH.D
PRIMARY EXAMINER